

REMARKS

Status of Claims

Claims 1, 3-11, 14-16, 19, 21-24, 31, 32 and 34-37 were pending. Pursuant to an election of species requirement, claims 3-6, 21, 22 and 31-37 were withdrawn from consideration. Claim 1 has been amended as shown above and claims 3, 4 and 21 have been canceled, without prejudice or disclaimer. Thus, claims 1, 5-11, 14-16, 19, 22-24, 31, 32 and 34-37 are pending as shown above.

Rejections Withdrawn

Applicants note with appreciation that the rejection under 35 U.S.C. § 102(b) based on Murayama has been withdrawn.

35 U.S.C. § 102(e)

Claims 1, 11, 14 and 19 were again rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 6,231,590 (hereinafter "Slaikeu").

As acknowledged by the Office, Slaikeu does not describe or demonstrate vaso-occlusive devices as recited in the amended claims. Accordingly, the rejection can be withdrawn.

35 U.S.C. § 103

Claim 15 was rejected under 35 U.S.C. § 103(a) as allegedly obvious over Slaikeu in view of U.S. Patent No. 5,891,192 (hereinafter "Murayama"). (Office Action, paragraph 5). Claims 1, 7, 8, 9, 10, 23 and 24 were again rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,690,666 (hereinafter "Berenstein") in view of U.S. Patent No. 4,414,976 (hereinafter "Schwarz"). (Office Action, paragraph 6). In addition, claim 16 was again rejected as allegedly obvious over Slaikeu in view of U.S. Patent No. 6,256,979 (hereinafter "Nikolchev"). (Office Action, paragraph 7). Claim 31 was rejected as allegedly obvious over Berenstein in view of WO 00/27445 (hereinafter "Boock"). (Office Action, paragraph 8).

Applicant addresses the rejections in turn.

Slaikeu in view of Murayama

Claim 15 was rejected as allegedly obvious over Slaikeu in view of Murayama. Slaikeu was cited as above for disclosing cytokines and Murayama was cited for teaching ion implantation.

The foregoing amendments to the claims obviate rejections based on Slaikeu. Therefore, Slaikeu, alone or in combination with Murayama, cannot render pending claim 15 obvious.

Schwarz

Claims 1, 7, 8, 9, 10, 23 and 24 were rejected as allegedly obvious over Berenstein in view of Schwarz. (Office Action, paragraph 6). Berenstein was again cited for allegedly disclosing a vaso-occlusive coil that is used with a tissue adhesive while Schwarz is cited for teaching that a surgical tissue adhesive can be made with Factor XIII, plasminogen activator or plasmin inhibitor in order to stimulate wound healing. *Id.* It is alleged that it would have been obvious to provide the device of Berenstein with the tissue adhesive of Schwarz in order to promote wound healing. *Id.*

Applicants note with appreciation the Examiner's pointing out that Applicants were looking at the previously cited Schwarz reference, namely Schwarz '507. (Office Action, paragraph 10).

In any event, the fact remains that Berenstein doesn't teach or suggest use of the bioactive materials recited in the claims. Rather, Berenstein's tissue adhesives are cyanoacrylate polymer resins, not the thrombus-stabilizing proteins as recited in claims 1, 7, 8, 9, 10, 23 and 24 (see, col. 5, line 66 to col. 6, line 6 of Berenstein, emphasis added):

Additionally, this process may include the step of introducing polymer resins, such as cyanoacrylate resins (particularly n-butylcyanoacrylate) to the intended site after the inventive coils or braids are in place. Said another way, the inventive coils or braids form a substrate for **these** tissue adhesives, or particulate embolization materials such as microparticles of polyvinyl alcohol foam, or various chemotherapeutic agents.

Thus, Berenstein provides no disclosure about the thrombus-stabilizing molecules and, moreover, provides no reason to combine its disclosure of cyanoacrylate resins with Schwarz's disclosure of tissue adhesives made from Factor VIII.

It is well settled that an obviousness rejection cannot be sustained when the references do not provide the suggestion to combine. *See, e.g., Smiths Industries Medical Systems, Inc. v. Vital Signs, Inc.* 51 USPQ2d 1415, 1420-1421 (Fed. Cir. 1999); *In re Fine*, 5 USPQ2d 1596, 1600

(Fed. Cir. 1988) and *In re Napier* 34 USPQ2d 1782, 1784 (Fed. Cir. 1995). It is also improper to base on obviousness rejection on an allegation that the general level of skill in the art was high and, accordingly, the motivation is present. *See, e.g., In re Rouffet*, 47 USPQ2d 1453 (Fed. Cir. 1998).

Thus, in the pending case, the statement that it would have been obvious to combine Berenstein and Schwarz "in order to promote healing" cannot form the basis of the rejection. There is nothing in Berenstein about promoting healing and nothing in Schwarz about vaso-occlusive compositions. Accordingly, a skilled artisan would not have been motivated to combine Berenstein's cyanoacrylate tissue adhesives for use in occlusion with Schwarz's protein-containing tissue adhesives (used to "seamlessly connecting tissue or organ part, sealing wound, stopping bleeding and stimulating wound healing," see, claim 1 of Schwarz).

In sum, a *prima facie* case of obviousness cannot be established because there is no reason to combine Berenstein's and Schwarz's disclosures. Accordingly, Applicant requests that this rejection be withdrawn.

Slaikeu in view of Nikolchev

Claim 16 was again rejected under 35 U.S.C. § 103(a) as allegedly obvious over Slaikeu in view Nikolchev. (Office Action, paragraph 7). Slaikeu was cited as above for allegedly disclosing the claimed invention except for the vaso-occlusive member being micro-textured. *Id.* Nikolchev is cited for disclosing micro-texturing in order to promote tissue ingrowth and enhance the occlusion of a vessel. *Id.*

As noted above, the foregoing amendments to the claims obviate rejections based on Slaikeu. Therefore, Slaikeu, alone or in combination with Nikolchev, cannot render pending claim 16 obvious.

Boock

Claim 31 was again rejected as allegedly obvious over Berenstein in view of Boock. (Office Action, page 4). Berenstein was cited as above and Boock was for teaching a bioactive material attached to a vaso-occlusive coil in order to reduce friction. *Id.*

As a threshold matter, Applicants note this rejection was originally made in the Final Office Action mailed October 8, 2003. Applicants argued the rejection and it was not reiterated in the Action on the merits (mailed April 28, 2004) following filing of an RCE. Thus, the rejection has previously been overcome and should not be raised again.

For the Examiner's convenience, Applicants reiterate the previously persuasive arguments herein. Berenstein fails entirely to teach or suggest using a vaso-occlusive composition comprising a vaso-occlusive coil, a liquid embolic material and an additional bioactive material, as set forth in claim 31. Berenstein also contains absolutely no suggestion that the "drug" be a bioactive material as set forth in pending claim 31. Moreover, there is certainly no suggestion that the drug be attached to the vaso-occlusive member, as required by these claims. Indeed, Berenstein teaches away from attachment, stating clearly that the liquid embolic material and/or "drug" is infused into the vessel **after** deployment of the ultrasoft embolic coils (*see, e.g.*, Abstract; col. 3, lines 14-24, particularly lines 18-20; and col. 4, lines 42-45).

Thus, the Examiner's reliance on the term "drug" as allegedly providing the motivation to combine this reference with Boock (or any other reference teaching bioactive materials as set forth in these claims) is entirely misplaced -- there is absolutely no teaching or suggestion in Berenstein regarding either the nature of the drug or that the drug is attached to the coil in any way, merely that it "fills" the interior space. Simply put, Berenstein does not teach or suggest the elements of the pending claims and does not provide the motivation to combine its disclosure with Boock's.

Boock fails to provide what is missing from Berenstein. Not only does Boock require an inner tie layer between the bioactive material and the vaso-occlusive member, it is also completely silent as to particulate liquid embolics set forth in pending claim 31. Furthermore, just as Berenstein's disclosure of the generic term "drug" would not have lead one to combine disclosures with Boock, there is no motivation in Boock to combine its disclosure with Berenstein. Furthermore, even if the disclosures were to be combined, such a combination would not lead to the claimed subject matter because there is no suggestion in either reference that the bioactive material be adsorbed to the vaso-occlusive member, as claimed.


Therefore, the rejection was (and is) unsustainable because no suggestion in the references to make the combination. Berenstein's alleged suggestion of using a drug would not reasonably point one of the skill in the art to Boock's devices in which the bioactive material is attached via a tie layer to the device. Since there is no motivation to combine the various teachings of Berenstein and Boock and since the combination of these references would not result in the composition of claim 31, the *prima facie* case of obviousness was properly withdrawn in April 2004 and should not now be reapplied.

CONCLUSION

In view of the foregoing remarks, Applicant believes the claims are in condition for allowance and requests early notification to that effect. In addition, Applicant requests that the withdrawn claims be examined. If the Examiner believes there are any outstanding issues, she is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

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